

James R. Condo (#005867)  
Kristine L. Gallardo (#033975)  
SNELL & WILMER L.L.P.  
One Arizona Center  
400 E. Van Buren, Suite 1900  
Phoenix, Arizona 85004-2202  
Telephone: (602) 382-6000  
Facsimile: (602) 382-6070  
jcondo@swlaw.com  
kgallardo@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)  
Georgia Bar No. 545599  
Matthew B. Lerner (admitted *pro hac vice*)  
Georgia Bar No. 446986  
NELSON MULLINS RILEY & SCARBOROUGH LLP  
201 17th Street, NW / Suite 1700  
Atlanta, GA 30363  
Telephone: (404) 322-6000  
Facsimile: (404) 322-6050  
richard.north@nelsonmullins.com  
matthew.lerner@nelsonmullins.com

*Attorneys for Defendants*  
*C. R. Bard, Inc. and*  
*Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability  
Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS C. R. BARD, INC.  
AND BARD PERIPHERAL  
VASCULAR, INC.'S MOTION TO  
EXCLUDE THE TINLIN CASE-  
SPECIFIC OPINIONS OF ROBERT  
M. McMEEKING, PH.D, AND  
SUPPORTING MEMORANDUM OF  
LAW**

(ASSIGNED TO THE HONORABLE  
DAVID G. CAMPBELL)

(TINLIN BELLWETHER CASE)

(ORAL ARGUMENT REQUESTED)

Pursuant to Fed. R. Evid. 702, and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and its progeny, Bard respectfully moves to exclude certain alleged case-specific opinions of Robert M. McMeeking, Ph.D. (“Dr. McMeeking”). Bard’s Motion is supported by the following Memorandum of Points and Authorities and any oral argument the Court may entertain.

## **MEMORANDUM OF POINTS AND AUTHORITIES**

### **I. INTRODUCTION**

In Dr. McMeeking’s MDL Report, and at each of the three bellwether trials, he offered general opinions criticizing the testing and design of Bard’s retrievable IVC filters, including the Recovery Filter. In *Tinlin*, however, Dr. McMeeking goes significantly farther, offering the granular, case-specific opinion that Bard’s alleged failure to incorporate certain safety features in the Recovery was the cause in fact of her claimed injuries. Specifically, Dr. McMeeking opines that caudal anchors, penetration limiters, a two-tiered design, and a “better” chamfer at the cap would have somehow prevented Ms. Tinlin’s filter from failing or minimized the risk of failure. (Ex. A, McMeeking Report at 3.) He then identifies certain competitor filters that allegedly incorporate these designs. (*Id.*)

However, Dr. McMeeking’s case-specific opinions are nothing but speculation. In his deposition, he admitted he cannot say these design changes would have prevented Ms. Tinlin’s injuries, and he does not know by what percentage the risk would be reduced. Indeed, he cannot say Ms. Tinlin would have avoided her injuries if one of the different filters he identified had been used. He conceded he has done no testing, analysis, drawings, diagrams, or calculations at all, and did not even consider Ms. Tinlin’s unique anatomy in formulating his opinions, even though he concedes that anatomical variances may impact the effectiveness of his proposed designs. Instead of providing true “case-specific” opinions, Dr. McMeeking simply repackaged his general opinions and conducted no further work. As a result, Dr. McMeeking’s opinions are no more tailored to Ms. Tinlin than they are to any other plaintiff who received a Recovery Filter.

For the reasons that follow, Bard respectfully asks this Court to exclude the Dr. McMeeking opinions regarding: (1) Alternative designs, including whether any specific alternative design would have reduced the risk of complications experienced by Ms. Tinlin; and (2) Bard's alleged "choices" in designing the Recovery without the design attributes that Dr. McMeeking alleges are better alternatives.

## **II. FACTUAL BACKGROUND**

### **A. Ms. Tinlin's complicated medical history and unique anatomy**

Debra Tinlin has a complicated medical history. Dr. Christopher S. Morris, Bard's expert interventional radiologist, summarized Ms. Tinlin's history in part as follows:

Debra Ann Tinlin is an obese, wheel chair dependent 54-year-old woman with multiple medical problems, including a severe debilitating neurologic disorder that has been diagnosed as multiple sclerosis by some neurologists, degenerative lumbar spondylosis with degenerative disk disease, thoracic myelopathy, syringomyelia, asthma, diabetes mellitus, hypercholesterolemia, hypertension, hypothyroidism secondary to treated Grave's disease, gastroesophageal reflux, obstructive sleep apnea, osteoarthritis, pernicious anemia, Sjogren's syndrome, history of nine miscarriages, uterine and rectal prolapse, depression, and a hypercoagulable state (familial thrombophilia) due to prothrombin 20210 gene mutation, treated with life-long systemic anticoagulation.

(Ex. B, Excerpts from Expert Report of Christopher S. Morris, MD, Jan. 5, 2019, at 2.)

On April 21, 2005 Ms. Tinlin was diagnosed with bilateral lower extremity acute deep vein thrombosis. (*Id.* at 3.) After she subsequently developed severe chest pain and shortness of breath, a May 5, 2005 CT angiogram revealed life-threatening bilateral pulmonary embolism. (*Id.*) She was recommended to receive a "temporary" IVC filter. (*Id.*) On May 7, 2005, Dr. Joshua Riebe implanted a Recovery filter. (*Id.*)

Ms. Tinlin also has a unique anatomy. At the time of implantation, Dr. Riebe estimated Ms. Tinlin's IVC to be "between 28 and 29 millimeters, which was at the upper limits of cava size for a Recovery filter." (Ex. C, Excerpts from Dep. of Dr. Joshua Riebe, April 4, 2017, at 98:24-99:12.) Dr. Riebe further commented that Ms. Tinlin's "Cava is

1 rather prominent in transverse diameter.” (*Id.*) Ms. Tinlin’s filter ultimately fractured,  
2 with multiple struts moving to her heart and pulmonary arteries, and she subsequently  
3 underwent several surgical procedures. (Ex. B, Morris Report, at 5-6.)

4 **B. Dr. McMeeking’s case-specific opinions about Ms. Tinlin’s Recovery Filter**

5 In his *Tinlin* report, Dr. McMeeking opines, “Mrs. Tinlin’s Recovery filter  
6 experienced all of the failure modes consistent with the defects inherent in the Recovery  
7 filter.” (Ex. A, McMeeking Report at 2.) He alleges that Ms. Tinlin’s Recovery filter  
8 lacked certain safety features that, if present, would have prevented her filter from failing  
9 or minimized the risk. (*Id.* at 2-3.) Specifically, Dr. McMeeking opines as follows:

10 A reasonably prudent engineer could have incorporated design features that  
11 were known in the field prior to when Mrs. Tinlin received her filter, and  
12 incorporation of these features would have helped to mitigate or eliminate  
13 the failures I have identified and that occurred in Mrs. Tinlin’s filter.  
14 Specifically, reasonable alternative designs and alternative features  
15 available to Bard before Mrs. Tinlin received her filter include many  
16 features that I have previously identified in my reports and deposition  
17 testimony: caudal anchors, penetration limiters, two-tiered design, and  
18 a better (smoother and rounded) chamfer at the mouth of the “cap” on  
19 the filter. Many of these design features existed in other IVC filter  
20 products already on the market, including the Simon Nitinol Filter, the  
21 Cook Gunther Tulip filter, the Greenfield filter, and the Cook Bird’s  
22 Nest filter.

23 (*Id.* at 3 (emphasis added).) But as discussed below, Dr. McMeeking did nothing to  
24 scientifically verify or validate these opinions.

25 **C. Dr. McMeeking did not consider Ms. Tinlin’s medical history or anatomy**

26 The opinions in Dr. McMeeking’s case-specific expert report are represented to be  
27 of a different type than those he disclosed in his Generic MDL Report. In other words, his  
28 report in *Tinlin* is purportedly not about whether a Recovery Filter may fail in a  
theoretical sense in some hypothetical person typical of the population of patients that  
might receive a Recovery Filter. Rather, his opinions in this case ostensibly pertain to  
Ms. Tinlin’s specific filter, the reasons why *her* filter failed, and the safety features that, if  
employed, would have prevented those actual failures or mitigated the risks to *her*.

Although Dr. McMeeking acknowledges that anatomical variances or other patient-  
specific factors may impact the efficacy of his purported alternative designs, (*see, e.g.,*

Ex D, Dep. of Robert McMeeking, Ph.D. (Rough Draft 1/30/19), at 15:13-24), he did not think “any specific health condition[]” of Ms. Tinlin’s was “important” to him in “coming up with [his] opinions.” (*Id.* at 57:20-24). Indeed, Dr. McMeeking’s expert report contains no medical history at all. The only portion of the report specific to Ms. Tinlin is a list of ten bullets (that he obtained from Dr. Hurst) starting on page one that describes her filter implantation on May 7, 2005, and then details the various filter failures that subsequently occurred. (*See* Ex. A, McMeeking Report, at 1-2.)

Critically, Dr. McMeeking did not factor in any specifics about Ms. Tinlin when purportedly arriving at his “case-specific” opinions in this matter.

**First**, he acknowledges that anatomical variances and other patient-specific factors may impact the effectiveness of his alleged alternative designs, testifying as follows:

- That the size of the IVC could impact the effectiveness of caudal anchors, penetration limiters, and two-tiered design (Ex. D, McMeeking Dep., at 15:13-24);
- He is unsure whether motion of the IVC may impact the effectiveness of caudal anchors, penetration limiters, and two-tiered design (*id.* at 16:15-17:3); and
- He is unsure whether the position of a patient’s spine impacts the effectiveness of caudal anchors, penetration limiters, two-tiered design, or rounded cap (*id.* at 17:24-19:2).

**Second**, he testified he did not consider Ms. Tinlin’s unique anatomy:

- He was not aware that Ms. Tinlin’s doctors recommended a retrievable filter (*id.* at 45:21-23);
- He did not independently assess the size of Ms. Tinlin’s IVC (*id.* at 25:6-9), and has no information regarding the size of her IVC at the date of implant (*id.* at 26:21-24);
- He agrees that “tilt and perforation can occur more readily if the Recovery filter is implanted in a patient with an inferior vena cava filter of greater diameter than the device is indicated for” (*id.* at 28:17-22);

- If Ms. Tinlin’s IVC was larger than 28mm, it “could have contributed to . . . failures of that filter” (*id.* at 34:3-7);
- Yet Dr. McMeeking’s report does not “outline the specific health conditions” of Ms. Tinlin (*id.* at 57:9-13);
- Dr. McMeeking did not feel that “any specific health conditions that [Ms. Tinlin] suffers that might have impacted her filter or its performance” were “important” to his opinions (*id.* at 57:20-24);
- He has “no idea whether Mrs. Tinlin suffered from any particular health condition that could have increased the likelihood that her Recovery filter would have tilted, migrated, perforated, or fractured” (*id.* at 57:25-58:4); and
- Nothing in his report “discuss[es] how caudal anchors or penetration limiters would operate in a situation where the inferior vena cava is larger than indicated for the filter” (*id.* at 34:21-25).

**Third**, he conducted no testing or analyses to take into account Ms. Tinlin’s unique anatomy:

- He has no “calculations for a vena cava filter with a diameter of 25 millimeters” or larger (*id.* at 65:1-10);
- He can’t say what the “maximum strain would be with a vena cava diameter of 28 millimeters” (*id.* at 65:23-66:2); and
- He has no “calculations of strain with regard to a filter operating in a 28 millimeter vena cava” (*id.* at 66:6-13).

**Fourth**, and finally, because Dr. McMeeking did not factor in any specifics about Ms. Tinlin when purportedly arriving at his “case-specific” opinions in this matter, he is unable quantify the impact his purported alternative designs would have had on reducing the risk of harm to Ms. Tinlin, or whether such risk would have been eliminated:

- He is unable to “say to a reasonable degree of engineering certainty that the design changes [he discusses] in [his] report would have prevented Mrs. Tinlin’s injuries” (*id.* at 56:25-57:4);

- Dr. McMeeking “cannot say by what percentage the risk would have been reduced with these design changes” (*id.* at 57:5-8);
- Dr. McMeeking cannot say that other filters, specifically the SNF, Greenfield, Tulip, or Bird’s Nest filters are “viable options” for Ms. Tinlin (*id.* at 49:1-5 (SNF), 49:8-9 (Greenfield), 49:10-16 (Tulip), 49:18-21 (Bird’s Nest));
- Dr. McMeeking cannot say “whether any retrievable filter available on the market at that time would have been a better option, or a viable option, for Mrs. Tinlin given her particular medical situation” (*id.* at 49:23-50:2);
- Dr. McMeeking cannot say whether “Mrs. Tinlin’s risk for injuries would have been reduced had she received a Tulip or Bird’s Nest filter” (*id.* at 52:4-7); and
- Dr. McMeeking cannot say whether the Greenfield filter has a lower risk of tilt, migration, perforation, fracture, or embolization compared to the Recovery (*id.* at 52:8-15).

**D. Dr. McMeeking did no testing, analyses, or calculations in forming his opinions regarding “alternative designs” or “alternative features”**

Dr. McMeeking offers a combination of four alternative design “features”: Caudal anchors, penetration limiters, two-tiered design, and a better (smoother and rounded) chamfer at the mouth of the “cap” on the filter. (Ex. A, McMeeking Report, at 2-3.) He also offers four filters as alternative designs or containing some of his alternative design features: the SNF, Tulip, Greenfield, and Bird’s Nest filters. (*See id.*) Despite opining on these “alternative designs,” Dr. McMeeking performed no testing, analyses, or calculations of any type in formulating his opinions about these purported alternative designs for Ms. Tinlin, and whether they would have prevented or reduced her risk of injury.

**i. Dr. McMeeking’s design features**

Dr. McMeeking testified as follows regarding his alternative design features:

**First**, Dr. McMeeking testified that he performed no testing or calculations on these alternative design features:

- Dr. McMeeking admits that his design features such as caudal anchors and penetration limiters “need to be designed to be effective” (Ex. D, McMeeking Dep., at 76:23-77:2);
- He agrees that a manufacturer must conduct some “design and testing” of design features to ensure they “do not compromise the safety or effectiveness of the device” (*id.* at 70:8-19);
- Yet, Dr. McMeeking conducted no “testing or any calculations to quantify the extent to which [caudal anchors, penetration limiters, two-tiered design, and rounded cap] would reduce the risk of complications in a patient” (*id.* at 111:20-24);
- No testing or calculations “to quantify the extent to which those design attributes would reduce the risk of complications in a patient with an IVC greater than 28 millimeters in diameter” (*id.* at 111:25-112:5);
- No bench testing of any sort (*id.* at 72:18 (“I don’t do bench testing”));
- No animal testing of any sort (*id.* at 73:5 (“I do no animal testing”));
- “No additional testing” for report in *Tinlin* (*id.* at 58:24-59:1);
- “No additional calculations” for report in *Tinlin* (*id.* at 59:2-4);
- No “calculations focused specifically on caudal anchors and what effect they would have in improving the performance of the filter” (*id.* at 43:15-18; *see also id.* at 53:19-23);
- No “specific calculations regarding the effect that penetration limiters would have on the filter” (*id.* at 43:19-22; *see also id.* at 54:9-14);
- No testing to determine whether significantly increased penetration limiters would be feasible in terms of delivery or retrieval (*id.* at 75:19-76:1);
- No “specific calculations as to the effect that a two-tiered design would have on the filter” (43:23-44:1; *see also* 54:25-55:4);
- No testing to verify that a better chamfer “would make a difference to the levels of strain that are generated” (16:5-14; *see also* 18:5-10);

- No calculations to “quantify the extent to which a cap would have reduced the risk to Mrs. Tinlin of sustaining the injuries” (*id.* at 55:10-14); and
- He is not familiar with Bard’s testing for developing “initial designs for limiters and anchors” (*id.* at 70:20-23).

**Second**, Dr. McMeeking offers no specificity, drawings, or other details concerning his alternative designs:

- Dr. McMeeking acknowledges that not all caudal anchors, penetration limiters, or two-tiered designs are of the same size, design, or effectiveness (*id.* at 40:10-41:4);
- For instance, Bard’s Denali filter has caudal anchors and penetration limiters, but Dr. McMeeking considers the filter defective (*id.* at 67:16-23; 71:10-15);
- Dr. McMeeking himself is capable of “creating design drawings of attributes for the filter” (*id.* at 40:6-9);
- But, Dr. McMeeking provided no proposed dimensions, designs, or drawings of a two-tiered design for Recovery, caudal anchors, or penetration limiters (*id.* at 41:5-23; *see also id.* at 77:12-15);
- Dr. McMeeking has devised no prototypes, for example, for penetration limiters (*id.* at 75:12-15); and
- Dr. McMeeking has not even compared his design features such as caudal anchors or penetration limiters to similar features with other devices, such as Denali, SNF, etc. (*id.* at 77:16-78:5).

**Third**, Dr. McMeeking offers no evidence that his design alternatives are feasible and, hence, reasonable:

- Aside from the Tulip filter, which Dr. McMeeking considers defective, (*see id.* at 68:14-17), he is unaware of “any IVC manufacturer who incorporated anchors or limiters in a retrievable filter prior to 2005” when Ms. Tinlin received her filter (*id.* at 69:12-17); and

1 **Fourth**, none of Dr. McMeeking’s opinions regarding design features are  
2 published in peer-reviewed literature or recognized standards:

- 3 • No “publications that analyze from an engineering perspective how caudal  
4 anchors or penetration limiters perform” (*id.* at 59:18-21), including none  
5 published by himself (*id.* at 59:22-60:1);
- 6 • Dr. McMeeking’s “opinions regarding those design alternatives [penetration  
7 limiters, caudal anchors, two-tiered design, or rounded chamfer] have not been  
8 peer reviewed” (*id.* at 60:2-5); and
- 9 • No “industry standards or governmental regulations that require those specific  
10 design features [penetration limiters, caudal anchors, two-tiered design, or  
11 rounded chamfer]” (*id.* at 60:15-22).

## 12 **ii. Dr. McMeeking’s alternative filters**

13 Although Dr. McMeeking identifies the SNF, Greenfield, Bird’s Nest, and Tulip as  
14 purported alternative designs for Ms. Tinlin, he has conducted no testing, analyses,  
15 calculations, or other work to confirm their effectiveness as alternative designs.

16 **SNF:** Dr. McMeeking violates this Court’s prior *Daubert* Order, Docket  
17 No. 10051, in which -- by agreement from Plaintiffs’ counsel -- Dr. McMeeking is  
18 precluded from identifying the SNF as a safer alternative design “for any particular  
19 plaintiff.” *Id.* at 10. Bard previously argued that Dr. McMeeking is not qualified to offer  
20 such an opinion because he is not a medical doctor, (*see* Docket No. 7314, at 13), and  
21 “Plaintiffs agree[d].” (Docket No. 10051, at 10.) Notwithstanding this prior order,  
22 Dr. McMeeking identifies the SNF filter as an alternative design for Ms. Tinlin. This  
23 Court should reaffirm its prior Order and preclude Dr. McMeeking from offering this  
24 opinion.<sup>1</sup>

25 **Greenfield (A Permanent Only Filter):** Dr. McMeeking has done no analysis to  
26 determine what changes would need to be made to the Greenfield to make it retrievable.

27 <sup>1</sup> Additionally, Dr. McMeeking admits that he “cannot say that the Simon Nitinol filter  
28 would have been a viable option” for Ms. Tinlin. (Ex. D, McMeeking Dep., 49:1-5.)

(Ex. D, McMeeking Dep., at 50:9-12, 21-25.) He has “performed no calculations to determine whether the Greenfield filter has a lower risk” of tilt, migration, perforation, fracture, or embolization than the Recovery. (*Id.* at 52:8-15.) Due to Mrs. Tinlin’s medical conditions, he “cannot say that the [Greenfield] would have been a viable option for her.” (*Id.* at 49:1-9). And, for the same reason that Dr. McMeeking is not qualified (because he is not a medical doctor) to opine that the SNF is a reasonable alternative design for any particular plaintiff, he is not qualified to offer any opinions regarding the Greenfield filter for Ms. Tinlin.

**The Cook Filters (Tulip and Bird’s Nest (A Permanent Only Filter))<sup>2</sup>:**

Dr. McMeeking has testified in the past that “Cook’s filters tilt more than any other filters [on] the marketplace.” (*Id.* at 51:4-8.) And, he has “filed a report in the Cook litigation that the Gunther Tulip filter is defectively designed.” (*Id.* at 68:14-17.) Even assuming this fact alone does not preclude these filters as reasonable alternatives for Ms. Tinlin, Dr. McMeeking has “done no analysis to determine what changes [he] would have to make to the Bird’s Nest to make it retrievable.” (*Id.* at 50:21-25.) And, regarding the Tulip, he admitted the Recovery has a significantly longer time period during which it can be retrieved, and as a result, “might have a superior medical benefit for some patients over a filter that had to be removed in seven to ten days.” (*Id.* at 48:6-11.) He did not know whether that was the case with Mrs. Tinlin. (*Id.* at 48:12-14.)

Glaringly, Dr. McMeeking also “cannot say one way or the other whether Mrs. Tinlin’s injuries would have been avoided” or whether her “risk for injuries would have been reduced” had she received a Bird’s Nest or the allegedly defective Tulip filter. (*Id.* at 51:23-52:7) This is because he has “performed no calculations in this case to determine whether the [Tulip or Bird’s Nest filter] has a lower risk” of tilt, migration, perforation, fracture, or embolization than the Recovery. (*Id.* at 52:16-53:9).

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<sup>2</sup> For the same reason that Dr. McMeeking is not qualified to opine that the SNF or Greenfield are reasonable alternative designs for any particular plaintiff, he is not qualified to offer any opinions regarding the Tulip or Bird’s Nest Filters for Ms. Tinlin.

1 Dr. McMeeking admitted that he doesn't know whether either of these filters "would have  
2 been a viable option" for Ms. Tinlin, (*id.* at 49:10-21), and that "I don't know whether [the  
3 Tulip Filter] would have been a better filter for her or not." (*Id.* at 48:15-21).

4 In summary, Dr. McMeeking conceded that the only alternative retrievable filter  
5 available at the time Ms. Tinlin needed one is a filter that he also claims is defective:

6 18 Q So, the only filter available at the time  
7 19 Mrs. Tinlin had her -- only retrievable filter available  
8 20 at the time she had her implant in 2005 that had limiters  
9 21 or anchors was the Cook filter that you have also opined  
10 22 is defective?  
11 23 MR. STOLLER: Object to the form.  
12 24 THE WITNESS: That's correct.

13 (*Id.* at 69:18-24.)<sup>3</sup>

### 14 **III. ARGUMENT AND CITATION OF AUTHORITY**

#### 15 **A. Legal standard**

16 For an expert's opinion to be admissible under Rule 702, the Court must find that  
17 "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of  
18 reliable principles and methods, and (3) the witness has applied the principles and  
19 methods reliably to the facts of the case." Rule 702 incorporates principles established in  
20 *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), in which the Supreme Court  
21 charged trial courts with a gatekeeping role to "ensure that any and all scientific testimony  
22 or evidence admitted is not only relevant, but reliable." *Id.* at 589. Ultimately, the  
23 objective of *Daubert* is "to make certain that an expert . . . employs in the courtroom the  
24 same level of intellectual rigor that characterizes the practice of an expert in the relevant  
25 field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

26 The proponent of expert testimony must demonstrate admissibility by a  
27 preponderance of proof. *Daubert*, 509 U.S. at 592 n. 10. And "nothing in either *Daubert*

28 <sup>3</sup> Bard understands the Court has limited time to review evidence, but respectfully suggests that the Court consider reading Dr. McMeeking's deposition transcript in its entirety (attached as Exhibit D), all of which cannot be included in this Motion, but will demonstrate the full extent of Dr. McMeeking's shortcomings under Rule 702.

1 or the Federal Rules of Evidence requires a district court to admit opinion evidence which  
2 is connected to existing data only by the *ipse dixit* of the expert.” *General Electric Co. v.*  
3 *Joiner*, 522 U.S. 136, 146 (1997). Under the above *Daubert* standard, Dr. McMeeking’s  
4 opinions discussed in this Motion are unreliable.

5 A fundamental requirement of Rule 702 is the proposed scientific testimony “assist  
6 the trier of fact to understand the evidence or to determine a fact in issue.” The Ninth  
7 Circuit has found that “[f]ederal judges *must . . . exclude* proffered scientific evidence  
8 under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to  
9 [the] issue in dispute in the case, and that it will not mislead the jury.” *Daubert v. Merrell*  
10 *Dow Pharms., Inc.*, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995) (emphasis added).

11 The *Daubert* Court identified four factors, among others, for consideration in  
12 determining the admissibility of expert opinions:

- 13 (1) Whether the theory or technique in question can be (and has been) tested;
- 14 (2) Whether it has been subjected to peer review and publication;
- 15 (3) Its known or potential error rate; and
- 16 (4) Whether it has attracted general acceptance in the scientific community.

17 *Daubert*, 509 U.S. 593-594. The Court further explained: “The inquiry is a flexible one,  
18 and its focus must be solely on principles and methodology, not on the conclusions they  
19 generate.” *Id.*

20 **B. The Court should exclude Dr. McMeeking’s opinions as pure speculation**  
21 **that will not assist the trier of fact because he cannot say his alternative**  
22 **designs or any different filter would have benefited Ms. Tinlin at all.**

23 As demonstrated in detail above, *see* Section II.C *supra*, Dr. McMeeking  
24 acknowledges that anatomical variances and other patient-specific factors may impact the  
25 effectiveness of his alleged alternative designs, yet he completely failed to take into  
26 account such potential variances and factors to determine whether his proposed alternative  
27 designs *fit* Ms. Tinlin’s case. Instead, he ignored her medical state, finding it not  
28 “important.” (Ex. D, McMeeking Dep., at 57:20-24; *see also* Section II.C, *supra*.) And

1 because Dr. McMeeking conducted no testing or analyses to take into account  
2 Ms. Tinlin's unique medical conditions, (*see, e.g.*, Ex. D, McMeeking Dep., at 65-1-10  
3 (no "calculations for a vena cava filter with a diameter of 25 millimeters" or larger); *see*  
4 *also* Section II.C, *supra*), he is unable quantify the impact his purported alternative  
5 designs would have had on reducing the risk of harm to Ms. Tinlin, or whether such risk  
6 would have been eliminated. (*See, e.g.*, Ex. D, McMeeking Dep., 56:25-57:4  
7 (Dr. McMeeking is unable to "say to a reasonable degree of engineering certainty that the  
8 design changes [he discusses] in [his] report would have prevented Mrs. Tinlin's injuries";  
9 *id.* at 57:5-8 (Dr. McMeeking "cannot say by what percentage the risk would have been  
10 reduced with these design changes").)

11 Likewise, Dr. McMeeking is unable to say whether **any** of his purported alternative  
12 filters -- SNF, Tulip, Greenfield, or Bird's Nest -- are "viable option[s]" for Ms. Tinlin.  
13 (*Id.* at 49:1-5 (SNF), 49:8-9 (Greenfield), 49:10-16 (Tulip), 49:18-21 (Bird's Nest).)  
14 Indeed, he admitted that he cannot say whether the Tulip, Bird's Nest, or Greenfield  
15 would have reduced the risk of harm to Ms. Tinlin. (*Id.* at 52:4-7 (Tulip and Bird's Nest),  
16 52:8-15 (Greenfield). And, Dr. McMeeking should be precluded from opining that SNF is  
17 an alternative design for Ms. Tinlin. *See* Dkt. 10051, at 10.

18 Finally, there is no dispute in this case that Ms. Tinlin was prescribed a retrievable  
19 filter. (*See, e.g.*, Ex. E, Excerpts of Plaintiff's Expert Report of Darren R. Hurst, M.D., at  
20 10 ("It was determined that she would receive a retrievable filter.") Yet Dr. McMeeking  
21 offered the fatal admission that he is "unable to say whether any retrievable filter on the  
22 market at that time would have been a better option, or a viable option, for Mrs. Tinlin  
23 given her particular medical situation." (Ex. D, McMeeking Dep., at 49:23-50:2.)

24 Unable to say whether any of his proposed alternative designs would help  
25 **Ms. Tinlin**, and admitting he cannot say any other filter was a better option for  
26 **Ms. Tinlin**, Dr. McMeeking's opinions provide the jury with no guidance. They do not **fit**  
27 this case. If presented with such opinions, the jury would be forced to guess whether these  
28 design features or other filters would had any impact on Ms. Tinlin at all. In other words,

1 maybe these features or other filters would help, and maybe they would not. Following  
2 Dr. McMeeking's deposition testimony, the answer to this question is anyone's guess.

3 **C. Dr. McMeeking's opinions regarding alternative design are unreliable**  
4 **because they fail of each of the four *Daubert* factors.**

5 **1. Dr. McMeeking did no testing, calculations, designs, or drawings.**

6 Courts nationwide, including courts in this District, exclude the opinions of design  
7 defect experts, like Dr. McMeeking, for failure to test the alternative designs they  
8 espouse. *See, e.g., Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017). In *Nease*, the  
9 plaintiff claimed that a design defect in the speed control system of their 2001 Ford  
10 Ranger caused the vehicle to crash. *Id.* 222. The plaintiff offered the expert testimony of  
11 Samuel Sero, an electrical engineer, who opined, among other things, that Ford's speed  
12 control system should have employed alternative design features available on other  
13 vehicles. *Id.* In striking similarity to this case, Mr. Sero admitted he conducted no testing  
14 of the alternative designs he contends would have been safer, instead relying on the fact  
15 that the alternatives at issue had long been available on the market:

16 Sero testified that several alternative speed control cable designs were  
17 available at the time and that Ford could have made the 2001 Ranger safer  
18 by incorporating one of these designs. **He admitted, however, that he had**  
19 **not tested any of these alternative designs to determine whether any of**  
20 **them would have prevented the accident in question. In Sero's opinion,**  
**testing of the alternative designs he identified was unnecessary because**  
**the designs had been in use in other vehicles for years and were**  
**therefore "proven commodit[ies]."**

21 *Id.* 226-27 (emphasis added). The district court denied the defendant's *Daubert* motion to  
22 exclude Mr. Sero, and entered a jury verdict in favor of the plaintiff.

23 The Fourth Circuit reversed, holding the district court failed to exercise its  
24 gatekeeping function and Mr. Sero's opinions should have been excluded as unreliable. In  
25 its analysis, the Court explained that, under *Daubert*, testing was an "especially important  
26 factor for guiding a court in its reliability determination." *Id.* 231. The Court was  
27 particularly focused on Mr. Sero's failure to test. *Id.* 234 ("This testimony should have  
28 been excluded as it was unsupported by any evidence such as test data."). The Court

1 rejected out of hand Mr. Sero's contention that he did not need to test the alternative  
 2 designs because they had long been in use. *Id.* ("The fact that the alternatives have  
 3 generally been in use for decades is wholly insufficient to prove that such designs were  
 4 safer ... and that reasonably prudent manufacturers would have adopted them."); *see also*  
 5 *Martinez v. Terex Corp.*, 241 F.R.D. 631, 638 (D. Ariz. 2007) (excluding alternative  
 6 design opinions of expert engineer when, *inter alia*, expert "did not perform any testing  
 7 regarding his proposed alternative design"); *Harrison v. Howmedica Osteonics Corp.*,  
 8 No. CIV 06-0745 PHX RCB, 2008 WL 906585 at \*14 (D. Ariz., March 31, 2008) (same).

9 Here, Dr. McMeeking admits that his design changes such as caudal anchors or  
 10 penetration limiters "need to be designed to be effective," (Ex. D, McMeeking Dep., at  
 11 76:23-77:2), and he freely acknowledges that a manufacturer must conduct some "design  
 12 and testing" of design features to ensure they "do not compromise the safety or  
 13 effectiveness of the device." (*Id.* at 70:8-19.) Yet, as discussed in detail above,  
 14 Dr. McMeeking did no testing, no calculations, no design, no drawings, no prototypes, no  
 15 comparisons, and provides no details or dimensions or specificity of any kind regarding  
 16 his alleged alternative designs. *See* Section II.D, *supra* (detailing Dr. McMeeking's failure  
 17 to perform any tests, analyses, or calculations for his opinions in this case). In other  
 18 words, Dr. McMeeking failed to employ the same type of intellectual and engineering  
 19 rigor he expects a manufacturer to use when identifying or utilizing potential design  
 20 features.

21 Likewise, Dr. McMeeking performed no analyses or calculations to determine  
 22 whether the Greenfield, Tulip, or Bird's Nest Filters have lower risk of tilt, migration,  
 23 perforation, or fracture compared to the Recovery filter that Ms. Tinlin received. (Ex. D,  
 24 McMeeking Dep., at 52:8-15; 51:23-52:7.) He performed no analysis or testing to  
 25 determine whether those filters could be changed to make them retrievable and useful for  
 26 Ms. Tinlin. (*Id.* at 50:9-12, 21-25.) And he openly admits that he believes the Tulip filter  
 27 is *defective*. (*Id.* at 68:14-17.) In other words, Dr. McMeeking's opinions regarding other  
 28 filters as potential alternative designs for Ms. Tinlin are not based on science, reliable

1 methodology, or -- in the case of the Tulip -- even common sense. Like the Court in  
 2 *Nease*, this Court should exclude Dr. McMeeking's opinions on alternative designs and  
 3 filters because he failed to test, analyze, or otherwise scientifically assess his opinions.

4 **2. Dr. McMeeking's opinions are unreliable because they are not peer-**  
 5 **reviewed, he cannot calculate a rate of error, and his opinions are not**  
 6 **generally accepted.**

7 There is no dispute that Dr. McMeeking has never published anything pertaining to  
 8 his opinions, which have not been peer-reviewed. (Ex. D, McMeeking Dep., at 60:2-5  
 9 (Dr. McMeeking's "opinions regarding those design alternatives [penetration limiters,  
 10 caudal anchors, two-tiered design, or rounded chamfer] have not been peer reviewed").)  
 11 And, Dr. McMeeking cannot point to a single piece of peer-reviewed literature that  
 12 supports his engineering opinions. (*Id.* at 59:18-21 (no "publications that analyze from an  
 13 engineering perspective how caudal anchors or penetration limiters perform."))

14 Additionally, because Dr. McMeeking performed no tests, calculations, or other  
 15 analyses, he cannot say whether the design features he advocates for would have  
 16 prevented Ms. Tinlin's injuries, and he cannot say "by what percentage the risk would  
 17 have been reduced," (*id.* at 57:5-8), or even whether his design changes would have had  
 18 any effect whatsoever. (*Id.* at 52:4-7.) As a result, Dr. McMeeking cannot show his  
 19 methodology is peer-reviewed, define its rate of error, or show that his method is  
 20 generally accepted. His opinions should be excluded as unreliable. *See Daubert*, 43 F.3d  
 21 at 1319 ("[T]he expert[] must explain precisely how they went about reaching their  
 22 conclusions and point to some objective source—a learned treatise, the policy statement  
 23 of a professional association, a published article in a reputable scientific journal or the  
 24 like—to show that they have followed the scientific method.").

25 **D. The Court should exclude Dr. McMeeking's improper opinions about**  
 26 **"choices" Bard allegedly made in designing the Recovery Filter.**

27 Dr. McMeeking opines that "Bard made a choice to design the Recovery filter  
 28 without caudal anchors [and penetration limiters]." (Ex. A, McMeeking Report, at 2.) He

has no evidence, however, “that Bard actually considered but then rejected caudal anchors as a design feature of the Recovery filter.” (Ex. D, McMeeking Dep., at 79:10-14; *see also id.* 80:11-14 (same regarding penetration limiters).) With respect to these so-called choices, Dr. McMeeking admitted he cannot testify as to Bard’s motives, intent, or state of mind. (*Id.* at 80:15-22.) Even if Dr. McMeeking could support these statements with documents, they are still improper expert testimony. The Court has excluded similar opinions in the past, and should do so again here. (*See, e.g.*, Dkt. 9770 at 6 (“Dr. Eisenberg will not be permitted to render opinions about what Bard did or should have done; to testify about Bard’s corporate knowledge internal conduct, or intent.”))

### CONCLUSION

For the foregoing reasons, Bard respectfully requests that this Court preclude Dr. McMeeking from offering opinions regarding alternative designs, including whether any specific alternative design would have reduced the risk of harm experienced by Ms. Tinlin, and opinions regarding Bard’s alleged “choices” in designing the Recovery Filter.

RESPECTFULLY SUBMITTED this 1st day of February, 2019.

s/Richard B. North, Jr.  
 Richard B. North, Jr.  
 Georgia Bar No. 545599  
 Matthew B. Lerner  
 Georgia Bar No. 446986  
 NELSON MULLINS RILEY & SCARBOROUGH, LLP  
 Atlantic Station  
 201 17th Street, NW / Suite 1700  
 Atlanta, GA 30363  
 PH: (404) 322-6000  
 FX: (404) 322-6050  
 richard.north@nelsonmullins.com  
 matthew.lerner@nelsonmullins.com

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James R. Condo (#005867)  
Kristine L. Gallardo (#033975)  
SNELL & WILMER L.L.P.  
One Arizona Center  
400 E. Van Buren  
Phoenix, AZ 85004-2204  
PH: (602) 382-6000  
FX: (602) 382-6070  
JCondo@swlaw.com  
KGallardo@swlaw.com

**Attorneys for Defendants C. R. Bard, Inc. and  
Bard Peripheral Vascular, Inc.**